REMARKS

Claim Status

Claims 1 - 10 are pending in the present application. No additional claims fee is believed to be due.

Claims 1, 6, and 8 have been amended to include the feature of information pertaining to the health of an individual. Support for this amendment can be found at page 15, lines 11 – 14 of the specification.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §112, First Paragraph

Claims 1 – 10 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action states that "the term 'medically relevant' is not described in the specification." The claims have been amended to remove the term "medically relevant," rendering the rejection moot. Applicants believe the amendment fully addresses the rejection stated in the Office Action.

Rejection Under 35 USC §112, Second Paragraph

Claims 1 – 10 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action states that "[t]he term 'medically relevant' in the claims renders them indefinite." The claims have been amended to remove the term "medically relevant," thus rendering the rejection moot. Applicants believe the amendment fully address the rejection stated in the Office Action.

Rejection Under 35 USC §103(a) Over Sheehan in View of Williamson

Claims 1 and 5 – 10 have been rejected under 35 USC §103(a) as being unpatentable over U.S. Pat. No. 6,319,199, issued to Sheehan, *et al.*, (hereinafter "Sheehan"). Applicants respectfully traverse the rejection.

It is well settled that in order to make out a *prima facie* case of obviousness, three requirements must be met. First, there must be some suggestion or motivation to combine the sources, second, there must be a reasonable expectation of success and lastly, the prior art references must teach or suggest all the claimed limitations of the present invention. MPEP §2143. It is Applicants position that the Office Action has failed to make a *prima facie* case of obviousness because there is no motivation to combine the cited references and the cited references do not teach each and every element recited in the claims of the present application.

Case law clearly states that "[i]t is improper to combine references where the references teach away from their combination. (MPEP §2145(X)(D)(2) citing *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). It is Applicants' position that the disclosure of Williamson is clearly contrary to that of Sheehan, thus rendering the combination of Sheehan and Williamson improper.

As best understood by Applicants, Sheehan is directed to a portable data collection device provided for image and data collection at a remote location. (Sheehan, abstract, emphasis added). Sheehan states "a patient can collect data at a leisurely pace and in familiar, comfortable surroundings." (Sheehan, col. 4, lines 39 – 40). Sheehan further states "[o]toscope 200 is used by a patient to perform a self-examination of an ear canal. The patient, at his or her own pace, may perform the examination at a remote location, such as the patient's home." (Sheehan, col.4, lines 51 – 53, emphasis added). Sheehan discloses that once the data is collected, it may be stored as records in memory and subsequently retrieved, transmitted and/or archived at any time convenient to the patient or doctor. (Sheehan, col. 7,

lines 40 – 42). Sheehan states "[t]his is especially significant in medical settings, as the need for many office visits is eliminated." (Sheehan, col. 7, lines 42 – 43, emphasis added).

In stark contrast, Williamson, as best understood by Applicants, is directed to an apparatus for sensing and displaying the duration of the Silent Periods of masticatory muscles, which is suitable for diagnostic applications made in a doctor's office. (Williamson, abstract, emphasis added). Williamson discloses a relatively lengthy multi-step process for making a diagnostic run. (Williamson, *see* generally col. 7, line 60 – col. 8, line 44). Williamson states "[f]or the temporalis muscle 10 the electrodes should be applied at a position just posterior to the frontal process of the zygomatic bone and the zygomatic process of the frontal bone." (Williamson, col. 8, lines 3 – 6). Williamson goes on to state "[w]hile the muscles are in flexed condition, the operator adjusts potentiometer 29 to set the gain at a predetermined level indicated on meter 31." (Williamson, col. 8, lines 11 – 13). Thus, Applicants submit that one of ordinary skill in the art would understand the diagnostic process of Williamson to require at least some level of medical/anatomical knowledge and at least two people (*i.e.*, a patient and an operator).

Additionally, case law states that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Applicants submit that modifying the patient-friendly otoscope of Sheehan to measure the Silent Periods of masticatory muscles as disclosed in Williamson would render the device of Sheehan unsatisfactory for use as a relatively simple-to-use, portable data collection device. Therefore, it is Applicants' position that the process of Williamson, directed to diagnostic applications made in a doctor's office, teaches away from the remote-use data collection device of Sheehan to the extent that the combination of Sheehan and Williamson is improper under the holding of *In re Grasselli*. (*In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

Notwithstanding the fact that the combination of Sheehan and Williamson is improper, there is still no teaching or suggestion of each and every element recited in the claims of the present application. With regard to claims 1, 2, and 5, Applicants assert that there is no teaching or suggestion of at least one data analysis mechanism generating information pertaining to the health of an individual wherein the data analysis mechanism performs at least one analysis selected from the group of: population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis, as is recited in claim 1 of the present application.

The Office Action states "[i]n Sheehan the data analysis mechanism is a group of population analysis because the images are compared to patterns or templates stored in the memory of the data acquisition and measurement device . . . ." (The Office Action, page 4, lines 5 – 6). However, Applicants submit that while Sheehan may disclose a device capable of comparing a digital image to a stored pattern or template, there is still no teaching or suggestion by Sheehan that such a comparison amounts to a population comparison, as recited in the claims of the present application. Applicants submit that one of ordinary skill in the art would appreciate that a population comparison generally requires a comparison of one individual to a population of at least one other individual, and that a population may include hundreds or even thousands of individuals. Applicants further submit that Sheehan does not teach or suggest that the patterns or templates are provided by even <u>one other</u> individual. Sheehan states "the images or patterns used by processor 208 for pattern matching are pre-recorded and stored on an external server or web page." (Sheehan, col. 7, lines 19 – 21). Therefore, the patterns or templates may be the individual's own images, which were pre-recorded and saved. Alternatively, the patterns or templates of Sheehan may not even be actual images from an individual, but artificial images created by a computer programmer or an artist.

In contrast with Sheehan, the present application states with regard to populations that

> Comparing data for a variety of health parameters to population data is significant in order to determine how far the individual's health parameters are from established baselines or from similar groups of individuals. Population data may include all humans for which data is available or specific subgroups of the overall population particularly relevant to the individual.

(The present specification, page 19, lines 14 – 18). Thus, it is Applicants' position that Sheehan does not teach or suggest each and every element recited in claim 1 of the present application. Applicants also assert that Williamson does not overcome the failings of Sheehan, and therefore the combination of Williamson and Sheehan does not teach or suggest each and every element recited in claims 1, 2, or 5 of the present application.

With regard to claim 6, Applicants note that the Office Action cites only Sheehan as teaching or suggesting each and every element recited in claim 6 of the present application. The Office Action cites Sheehan at col. 2, lines 34 – 46 and col. 8, lines 18 – 32 to support the assertion that Sheehan teaches the data acquisition mechanism recited in claim 6 of the present application. However, Applicants are unable to find any in teaching or suggestion in the cited portions of Sheehan or Williamson of at least one data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium wherein the at least one data acquisition mechanism is selected from the group: a tablet PC, voice recognition, and telemetry based systems, as recited in claim 6 of the present application.

The present specification states "[d]ata acquisition, as used herein, refers to the step of transferring the data from its source or initially recorded location to a data storage medium or system." (The present application, page 13, lines 2 – 4). The present application further refers to a data acquisition mechanism as "any device, system, or process capable of transferring data to the storage medium or system" (*i.e.*, performing the data acquisition function). (The present application, page 13, lines 5 – 10).

At col. 2, lines 34 – 46 Sheehan discloses, as best understood by Applicants, an environment within which the data collection device of Sheehan may operate. Specifically, an environment wherein a collecting party collects data and transfers the data to a central server that is accessible by a prescribing party. However, Applicants are unable to find in the

cited portion of Sheehan any teaching or suggestion that the data is necessarily relevant to a particular health condition, or that the data acquisition mechanism, which is selected from the group consisting of a tablet PC, voice recognition, and telemetry based systems, is performing the data transfer.

At col. 8, lines 18 – 32 Sheehan discloses, as best understood by applicants, a base unit 300 optionally comprising a communications port for communicating with a wide range of external devices. Sheehan states "[o]nce images have been collected with device 200 . . . image records may be downloaded from device 200 to base station 300 for later export to an external website, server, or host PC." (Sheehan, col. 8, lines 46 – 50). Thus, it is Applicants' position that the base unit of Sheehan is not a data acquisition mechanism as recited in claim 6 of the present application, but is rather a device that performs an intermediary data storage function as opposed to a data acquisition function. Consequently, Applicants assert that the cited portion of Sheehan fails to provide the requisite disclosure of data acquisition mechansism and that Williamson does overcome the lack of disclosure.

In light of the above remarks, Applicants further assert, with regard to claim 7, that neither Sheehan nor Williamson teach or suggest a data acquisition mechanism that includes a handheld device selected from the group of a PDA and a handheld PC, as is recited in claim 7 of the present application.

The remarks made above are equally applicable to claim 8. Specifically, that the cited portions of Sheehan and Williamson do not teach or suggest a data acquisition mechanism transferring data relevant to a particular health condition from a data measurement mechanism to a storage medium, as recited in claim 8 of the present application.

With regard to claim 9, the Office Action states "Sheehan teaches . . . analyzing the data via at least one data analysis mechanism to define out-of-control situation requiring intervention . . . wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison . . . ." (The Office Action, page 6, bottom – page 7, top). As pointed out above, it is Applicants' position that the portions of Sheehan cited in the Office Action do not teach or suggest a population comparison analysis, and Williamson

does not remedy this lack teaching or suggestion. Applicants assert that Sheehan does not teach or suggest a data analysis mechanism that analyzes data related to a health parameter to define and out-of-control situation.

The present specification generally refers to out-of-control situations as situations where health parameters fall outside of the specification limits (e.g., medical limits) or when statistically significant changes in the health parameter are identified. (The present application, page 18, lines 5 – 24). As best understood by Applicants, Sheehan discloses a device that captures an image and compares the image to a pattern or template in order to provide a signal that the image was of sufficient quality. It is Applicants' further understanding that the device of Williamson merely measures the Silent Period of a patient and displays the result apparently without performing any analysis, as recited in the present claims. Thus, neither Sheehan nor Williamson teach or suggest a data analysis mechanism that analyzes data related to a health parameter to define and out-of-control situation, as recited in claim 9 of the present application. The above remarks are equally applicable to claim 10 which depends from claim 9.

In light of the foregoing remarks, it is Applicants' position that the combination of Sheehan and Williamson is improper and that the Office Action has failed to make out a *prima facie* case of obviousness, or alternatively that the combination of Sheehan and Williamson does not teach each and every element of claims 1 – 2 and 5 – 10. Accordingly, Applicants respectfully request that the rejection of claims 1 – 2 and 5 – 10 be reconsidered and withdrawn.

Rejection Under 35 USC §103(a) Over Sheehan in view of Ekblad

Claim 3 has been rejected under 35 U.S.C. 103(a) over Sheehan in view of Ekblad (U.S. Pat. No. 5,920,478). Applicants respectfully traverse the rejection.

The Office Action states "Sheehan does not teach that the at least one data analysis mechanism further comprises automatic or triggered recalculation of control limits based on top demonstrated historical performances." (The Office Action, page 7, bottom). The Office Action cites Ekblad to overcome the failing of Sheehan. Even assuming, *arguendo*, that the

combination is proper, Applicants are unable to find any showing in the Office Acton that Ekblad cures Sheehan's lack of disclosure with regard to claim 1 of the present application. Thus there can be no teaching or suggestion of each and every element of claim 3 of the present application, which depends from claim 1. Therefore, Applicants respectfully request that rejection of claim 3 under 35 U.S.C. 103(a) over Sheehan in view of Ekblad be reconsidered and withdrawn.

Rejection Under 35 USC §103(a) Over Sheehan in view of Loman

Claim 4 has been rejected under 35 U.S.C. 103(a) over Sheehan in view of U.S. Pat. No. 6,642,592 issued to Loman, et al., (hereinafter "Loman"). Applicants respectfully traverse the rejection.

The Office Action states "Sheehan does not teach that the reliability engineering analysis includes time between failures and failure duration." (The Office Action, page 8, middle). The Office Action cites Loman to overcome the failings of Sheehan. However, Applicants assert that the combination of Sheehan and Loman is improper, and that a *prima facie* case of obviousness based on such combination must fail.

It is well settled that there are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. (MPEP §2143.01 citing *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998)). Applicants assert that there is no suggestion or motivation for one of ordinary skill in the art to combine the image capturing otoscope of Sheehan with the fault diagnosis system of Loman.

With regard to the nature of the problem to be solved, Applicant is unable to find any evidence that one of ordinary skill in the art would be motivated to combine Sheehan and Loman. As best understood by Applicants, Loman discloses a method for accessing a remote site by a field engineer faced with a machine fault in order to diagnose and repair the machine fault. (Loman, abstract). Loman states "the present invention resides in the novel combination of processing steps and hardware related to the diagnosis and repair of complex machines." (Loman, col. 3, lines 10 – 13). Since Sheehan discloses that the device of

Sheehan is functioning properly when an image is captured and when the image comparison takes place, Applicants are unsure why one or ordinary skill in the art would be motivated to modify the device of Sheehan with the fault diagnosis system of Loman. In other words, Applicants are unsure of what fault in the device of Sheehan the system of Loman would diagnose and repair. Therefore, absent any evidence to the contrary, it is Applicants' position that the nature of the problem to be solved in Sheehan and Loman do not provide any motivation to why one of ordinary skill in the art would combine the device of Sheehan and diagnostic system of Loman.

With regard to the teachings of the prior art, Applicants are unable to find any teaching in Sheehan or Loman why one of ordinary skill in the art would modify the data collection device of Sheehan with fault diagnosis system of Loman. Thus, absent any evidence to the contrary, it is Applicants' position that the motivation to combine Sheehan and Loman is not found in the teachings of Sheehan and Loman.

With regard to the knowledge of persons of ordinary skill in the art, Applicants are unable to find any reasoning or evidence in the Office Action as to why one of ordinary skill in the art of health-related data collection devices would be motivated to modify the otoscope of Sheehan with the fault diagnosis system of Loman.

Notwithstanding the fact that there is no motivation to combine Sheehan and Loman, Applicants' assert that such combination still does not teach each and every element of claim 4 of the present application. The remarks made above with regard to claim 1 are equally applicable to claim 4, which depends from claim 1. Since the disclosures cited in the Office Action fail to teach or suggest each and every element of claim 1 and Loman fails to overcome the lack of teaching or suggestion with regard to claim 1, Applicants assert that the combination of Sheehan and Loman fails to teach or suggest each and every element of claim 4.

Accordingly, Applicants respectfully request that the rejection of claim 4 under 35 U.S.C. §103(a) over Sheehan in view of Loman be reconsidered and withdrawn.

RECEIVED
CENTRAL FAX CENTER
MAR 2 8 2007

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied reference(s). In view of the foregoing, entry of the amendment(s) presented herein, reconsideration of this application, and allowance of the pending claim(s) are respectfully requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By _____
John Powell
Registration No. 57,927
(513) 634-2962

Date: March 28, 2007
Customer No. 27752